In the Application of:
Tony N. Frudakis

PATENT
Attorney Docket No.: DNA1180-2

Application No.: 10/589,291 Filed: June 4, 2007

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## **REMARKS**

Claims 1-5 and 7-28 are currently pending, with claims 4, 5, and 14-28 having been withdrawn from further consideration. By the present communication, no claims have been added, claim 4 has been canceled without prejudice, and claim 1 has been amended to define Applicants invention with greater particularity. Support for the amended claim language may be found throughout the specification and claims as filed. Upon entry of the present amendment, claims 1-3 and 7-13 will be under consideration.

Applicant thanks Examiner Goldberg for the telephonic interview held on October 13, 2010, during which strategies for amending the claims to overcome the outstanding rejections were discussed. The amendments and arguments presented herein are believed to adhere to the discussed strategy.

## **Priority**

Applicant respectfully traverses the allegation that the disclosures of PCT/US05/004513, U.S. Serial No. 60/544,788, and U.S. Serial No. 60/548,370 do not teach how to infer an eye color based upon an allele. The Office Action asserts that "[t]here is no teaching which allele is associated with which eye color." (Office Action, page 2). Without acquiescing to the reasoning of the Action, and in order to further prosecution of the instant application, Applicant has amended claim 1 to require identifying in the nucleic acid sample nucleotide occurrences of the eye color related single nucleotide polymorphisms (SNPs) shown in Table 2. Support for the amended claim language may be found at paragraph [0062] of the specification, which is identical to that of PCT/US05/004513.

Attached as Exhibit A is a scientific article authored by the inventor of the claimed subject matter, and incorporated by reference at Table 2 of the specification as filed (Exhibit A – Frudakis, *et al. Genetics* 165:2071-2083 (December 2003)). As shown in Exhibit A, Tables 2 and 3 provide one of skill in the art, in view of paragraph [0026] of the specification as filed, with data supporting inference of eye color. As such, Applicant submits that one of skill in the art would understand how to *infer* eye color based upon the SNPs listed in Table 2 of the specification as filed. Applicants respectfully request that the

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instant application be accorded at least the priority date of U.S. Serial No. 60/544,788, filed February 13, 2004.

## Rejections Under 35 U.S.C. §112, First Paragraph

Applicants respectfully traverse the rejection of claims 1-3 and 7-13 as allegedly failing to comply with the enablement requirement. Specifically, the Office Action indicates that "the specification, while being enabling for a method for detecting the SNP at nucleotide 68 of SEQ ID NO: 3 and nucleotide 171 of SEQ ID NO: 4, does not reasonably provide enablement for a method of inferring natural eye color in a human subject based upon detecting the SNP at nucleotide 68 of SEQ ID NO: 3 and nucleotide 171 of SEQ ID NO: 4.

As discussed above, without acquiescing the reasoning of the Action and in order to further prosecution of instant application, Applicant has amended claim 1 to recite a method for inferring natural eye color of a human subject from a nucleic acid sample of the subject, comprising identifying in the nucleic acid sample nucleotide occurrences of the eye color related single nucleotide polymorphisms (SNPs) shown in Table 2, and comparing the identified at least one nucleotide occurrence with known nucleotide occurrences of eye color related SNPs associated with known eye colors. Applicant respectfully directs the Examiner's attention to paragraph [0059] of the specification as filed, which describes

The iris color of a subject can be predicted from a nucleic acid sample by determining the genotype of the sample with respect to SNPs as shown in Table 2 (e.g., with one or more of the SNPs of SEQ ID NOS: 1 to 7); comparing the genotype against those for known subjects in a database (i.e., subjects for whom eye color has been associated with nucleotide occurrence(s) of the SNPs; and identifying known subjects whose genotypes match the unknown sample. The iris colors of the known subjects thus provide a guide.

As such, one of skill in the art, in view of the specification as filed, would understand how to infer natural eye color of a human subject by comparing the nucleotide occurrences of the eye color related SNPs listed in Table 2 with a panel of SNPs from subjects of known eye color.

The Office Action further alleges that "[t]he specification teaches that iris colors of 'unknown' samples based on genotypes of 35 SNPs provided a blind classification accuracy In the Application of: Tony N. Frudakis Attorney Docket No.: DNA1180-2

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of 97% when an exact match existed across all genotypes in Table 2. This seems to state that iris color could be inferred correctly 97% of the time if ALL 35 SNPs were correct."

As discussed during the telephonic interview, Applicant has amended claim 1 to recite a method for inferring natural eye color of a human subject from a nucleic acid sample of the subject, comprising identifying in the nucleic acid sample nucleotide occurrences of the eye color related single nucleotide polymorphisms (SNPs) shown in Table 2, and comparing the identified at least one nucleotide occurrence with known nucleotide occurrences of eye color related SNPs associated with known eye colors. Applicant respectfully directs the Examiner's attention to paragraph [0026] of the specification as filed, which states,

the Sequence Listing provides SNP marker numbers (e.g., RS2311470, see SEQ ID NO:1), which can be used to locate the exemplified SNP in a database such as that provided by the National Institutes of Health (see world wide web (www) at "ncbi.nlm.nih.gov"; SNP database). A target polynucleotide typically includes a SNP locus and/or a segment of a corresponding gene that flanks the SNP. Either the coding strand or the complementary strand (or both) comprising the SNP positions as set forth in SEQ ID NOS:1 to 48 can be examined such that an inference as to eye color or natural hair color can be drawn.

In addition, Exhibit A, as discussed above, and incorporated by reference at Table 2 of the specification as filed, provides additional data by which one of skill in the art would be able to infer eye color in view of the SNPs listed in Table 2.

Accordingly, Applicant respectfully submits that the specification provides an enabling disclosure for the claimed invention and requests withdrawal of the rejection.

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## **CONCLUSION**

In view of the foregoing amendments and the remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this case.

The Commissioner is hereby authorized to charge \$ .00 as payment for the Request for Continued Examination to Deposit Account No. 07-1896. No additional fee is believed due. If any additional fee is due, the Commissioner is hereby authorized to charge any fees required by this submission, or make any credits or overpayments, to Deposit Account No. 07-1896 referencing the above-identified attorney docket number.

Respectfully submitted,

Date: October 22, 2010

ANTONY M. NOVOM Rg. No. 45,517

Lisa A. Haile, J.D., Ph.D. Registration No.: 38,347 Telephone: (858) 677-1456 Facsimile: (858) 677-1465

DLA PIPER LLP (US) 4365 Executive Drive, Suite 1100 San Diego, California 92121-2133 **USPTO Customer No.: 28213**